Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Hebei HongSen Plastics Technology Co., Ltd
The Eastern Industrial Accumulation Area
Nangong City, Xingtai City, Hebei Province, China
Tel: 86- 311-85656588
Submitter's FDA Registration Number: N/A

SEP 25 2013

5.2 US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: April 15, 2013

5.4 Device Name:

Proprietary Name:	Powder Free Patient Examination Gloves, Blue Color (Brand Name: Titans)
Common Name:	Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel: General	Hospital
Product Code:	LZA

5.5 Predicate Device Information:

(1) K121992, "Patient Nitrile Examination Gloves, Powder Free, Non-Sterile, Blue Color", manufactured by "Xinwei (Shandong) Plastic and Rubber Products Co., Ltd."

5.6 Device description:

Powder free nitrile examination gloves are made of synthetic nitrile rubber, and are non sterile that meets all of the requirements of ASTM standard D 6319-10, except for sterility requirements. They have blue color.

5.7 Intended Use:

The Titans powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has blue color and is sold as non sterile.

5.8 Comparison to Predicate Devices

The powder free nitrile examination gloves, blue, non sterile are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K121992, "Patient Nitrile Examination Gloves, Powder Free, Non-Sterile, Blue Color", manufactured by "Xinwei (Shandong) Plastic and Rubber Products Co., Ltd."

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K121992)
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has blue color and is sold as non sterile.	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)
Basic Design	A garment covering the hand and waist area. Gloves have separate sheaths or openings for each finger and the thumb.	Same
Materials	Nitrile rubber	Same
Size	XS, S, M, L, XL, XXL	S, M, L,XL
Single Use	Yes	Yes
Color	blue	Blue
Sterile	Non sterile	None Sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, and material between our device and the predicate devices.

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Powder Free Patient Examination Gloves, Blue Color (Brand Name: Titans), manufactured by *"Hebei HongSen Plastics Technology Co., Ltd."* met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Physical, Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K121992)
Dimension	Meets ASTM D 6319-10 (Published 03/18/2011)	Meets ASTM D 6319-10 (Publication date unknown)
Physical Property	Meets ASTM D 6319-10 (Published 03/18/2011)	Meets ASTM D 6319-10 (Publication date unknown)
Free of Pinhole	Meets ASTM D5151 (AQL 2.5) (Published 08/20/2012)	Meets ASTM D5151 (Publication date unknown)
Residue Powder	Meets ASTM D6124 (Published 08/20/2012)	Meets ASTM D6124 (Publication date unknown)
Primary Skin Irritation (ISO 10993-10: 2010)	Not a primary skin irritant under the conditions of the study	Same
Dermal sensitization (ISO 10993-10: 2010)	Not a dermal sensitizer under the conditions of the study	Same

5.9 A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Powder Free Patient Examination Gloves, Blue Color (Brand Name: Titans) meet requirements per ASTM D6319-10, ASTM D6124-06, ASTM D 5151-06, and ISO 10993-10. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

5.10 A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

5.11 Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our Powder Free Patient Examination Gloves, Blue Color (Brand Name: Titans) are substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Hebei HongSen Plastics Technology Company Limited
C/O Charles Shen
Manton Business and Technology Services
5 Carey Street
PENNINGTON NJ 08534 US

Re: K131440
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue Color
(Brand Name Titans)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 11, 2013
Received: July 1, 2013

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

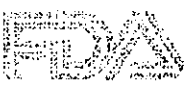
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131440

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue color (Brand Name: Titans)

Indications for Use *(Describe)*

The Titan powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has blue color and is sold as non sterile.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Elizabeth F. Claverie
2013.09.25 14:04:24 -04'00'